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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Maertens et al.

Atty. Ref.: 2551-109

Appl. No. 09/899,303

Group: 1648

Filed: July 6, 2001

Examiner: Bao Qun Li

For: PURIFIED HEPATITIS C VIRUS ENVELOPE PROTEINS FOR DIAGNOSTIC AND THERAPEUTIC USE

* * * * *

August 21, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RULE 181 PETITION

The Commissioner is requested to invoke his supervisory authority and have the restriction requirement of February 25, 2003 (Paper No. 15) withdrawn, and instructing the Examiner to examine all the pending claims or a substantial portion thereof as described herein and in the attached Amendment which is being filed in response to the Office Action of April 21, 2003.

The applicants responded to the restriction requirement of February 25, 2003, with their Response of March 25, 2003, electing, with traverse, the subject matter of the Examiner's Group I, drawn to a recombinant vector and a composition comprising the vector comprising a HCV envelope protein. The applicants further elected, with traverse, the single sequence of SEQ ID NO:7. Reconsideration and withdrawal of the

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restriction requirement were requested as the applicants believed, and continue to believe, that the Examiner's basis for the restriction requirement (i.e., that "each of the polypeptides recited in alternative forms is not member of a single genus of invention, it derives from different genome of each HCV isolates and each of them has different patentable weight") is technically incorrect. Specifically, the applicants pointed out that with the exception of SEQ ID NO:29 and SEQ ID NO:31, which are peptides derived from HCV type 3a and HCV type 5a, respectively, all other claimed SEQ ID NOs represent peptides of a single HCV polyprotein derived from a single genome sequence of the same single HCV isolate of type 1b. The applicants therefore requested rejoinder and examination of SEQ ID NO:7 with all the other recited SEQ ID NOs, except, perhaps SEQ ID NO:29 and SEQ ID NO:31. Reconsideration and withdrawal of the restriction requirement is therefore requested in this regard.

The applicants further elected, with traverse, vaccinia virus vectors, in response to the Examiner's requirement for such an election of a single vector. See, page 2 of Paper No. 15. Reconsideration and withdrawal of the restriction requirement in this regard was also requested as the applicants did not believe, and continue to not believe, that the various vectors define separately patentable subject matter and the applicants further believe that the limitation imposed by the Examiner will place an undue burden on the applicants in prosecuting separate applications.

In response to the applicants request for reconsideration and the Response dated March 25, 2003, the Examiner has made the restriction requirement final in the Office Action dated April 21, 2003 (Paper No. 18).

Reconsideration and withdrawal of the restriction requirement are requested and examination of all or at least a greater portion of the claimed subject matter for the reasons described herein are requested along with a grant of the present petition.

The Examiner's search has confirmed that the alleged separately patentable subject matter is described in references cited by the Examiner in the search of the elected subject matter. Accordingly, as asserted by the applicants in their Response of March 25, 2003, the applicants again submit that search and examination of all the claimed subject matter would not be an undue burden on the Examiner. Moreover, the Examiner's search confirms that the alleged separately patentable subject matter has not obtained a status in the art indicative of separate invention. The applicants note in this respect that only two different "inventions" were recognized during the International Phase of the parent PCT application (see, attached relevant portion of International Search Report). Claims 68-69, 88-89 and 96-97 are, at a minimum, therefore should be considered and are believed to be in condition for allowance.

As described in the remarks of the Amendment dated December 5, 2002, the applicants submit that a search of claim 67, for example, would necessarily reveal vectors comprising an E1 sequence other than the elected SEQ ID NO:7. The Examiner has maintained the election requirement of a single sequence. The applicants note however that all of the references cited by the Examiner in Paper No. 18 disclose vectors comprising an E1 sequence distinct from SEQ ID NO:7, or any of the other type 1b SEQ ID numbers of the presently claimed invention. Clearly therefore the sequences of the presently claimed invention define a single invention. Moreover, the applicants note that a search has revealed a variety of vectors in single references for a

variety of E1 sequences. The Examiner's requirement for an election of a single SEQ ID number and single vector should be withdrawn.

As also described in the remarks of the applicants' December 5, 2002 Amendment, a search of claim 67 would necessarily reveal vectors other than the elected vaccinia vectors. The Examiner has maintained the election requirement with regard to the vectors, as noted above. All of the claims 87-91 however are believed to continue to be under active consideration. Moreover, several references cited by the Examiner in Paper No. 18 disclose vectors other than vaccinia vectors for expression of E1 (i.e., baculovirus vectors: Matsuura, Shu et al., 1993, Lanford et al., 1993 and paragraphs numbered 16, 24 and 29, for example, of Paper No. 18; vectors for in vitro transcription: Hijikata et al., 1991, and paragraph 19 of Paper No. 18; vectors for expression of a protein in E. coli: Devare et al., Grakoui et al., 1993 and paragraphs numbered 26 and 36, respectively of Paper No. 18; adenovirus vector; Watanabe et al. and paragraph 43 of Paper No. 18). The restriction requirement with regard to the vector type should be withdrawn and the claims should be examined across their breadth without limitation of particular vectors.

Grant of the present petition and examination of all the pending claims are requested.

The requisite petition fee is attached.

Consideration of the present petition prior to issuance of a further Action on the merits is requested, to expedite examination.

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Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



B. J. Sadoff
Reg. No. 36,663

BJS:plb

1100 North Glebe Road, 8th Floor

Arlington, VA 22201-4714

Telephone: (703) 816-4000

Facsimile: (703) 816-4100